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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/750,022

**Applicant(s)**

ISAACS, INDU J.

**Examiner**

Chih-Min Kam

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-22,31-33,36,39,40,43,46,55,58,60-62,64 and 68-76 is/are allowed.
- 6) ☒ Claim(s) 2-4,23-30,34,35,37,38,41,42,44,45,47-54,56,57,59,63 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-76 are pending.

Applicants' amendment filed March 16, 2004 is acknowledged. Applicants' response has been fully considered. Claims 1, 25 and 52 have been amended, and new claims 56-76 have been added. Therefore, claims 1-76 are examined.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

2. The previous rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicants' response at page 14 in the amendment filed March 16, 2004, and applicant's response at page 4 in Paper No. 8.

#### ***Claim Rejections - 35 USC § 103***

3. The previous rejection of claims 1-10, 22, and 49-55 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* (U. S. Patent 6,120,761), is withdrawn in view of applicants' response at pages 14-18 in the amendment filed March 16, 2004.
4. The previous rejection of claims 11, 12, 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claims 1-10, further in view of Hora *et al.* (U. S. Patent 5,997,856), is withdrawn in view of applicants' response at pages 18-19 in the amendment filed March 16, 2004.
5. The previous rejection of claims 13-15, 17-20 and 32 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* and

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Hora *et al.*, as applied to claim 1, further in view of Drucker *et al.* (WO 97/39031), is withdrawn in view of applicants' response at page 19 in the amendment filed March 16, 2004.

6. The previous rejection of claims 16 and 21 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claim 1, further in view of Thim *et al.* (U.S. Patent 5,912,229), is withdrawn in view of applicants' response at pages 19-20 in the amendment filed March 16, 2004.

7. The previous rejection of claims 43-46 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claim 1, further in view of Drucker (U. S. Patent 5,952,301), is withdrawn in view of applicants' response at page 20 in the amendment filed March 16, 2004.

### ***Claim Objections***

8. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. For example, in claims 56 and 57, applicant has used "h[Gly<sup>2</sup>]GLP-2" in such a manner that appears that the instant brackets would indicate deleted material and is thus, confusing as to whether the GLP-2 peptide in claims 56 and 57 would include "Gly<sup>2</sup>" or not. The applicant can only amend by cancellation and presentation of a new claim. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)).

9. Claim 59 is objected to because of the use of terms "glu" and "PO<sub>3</sub>-Tyr<sup>2</sup>". Use of "Glu" and "PO<sub>3</sub>-Tyr" is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-4, 23-30, 34, 35, 37, 38, 41, 42, 44, 45, 47-54, 56, 57, 59, 63, 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 2-4, 34, 35, 37, 38, 44, 45, 50, 51, 56, 57, 65-67 are indefinite because of the use of the term “greater than about 6.0” or “greater than about 5.5”. The term “greater than about 6.0” or “greater than about 5.5” renders the claim indefinite, it is unclear whether the pH of the formulation is higher than pH 6.0 (or 5.5) as to “greater than”, or, is less than pH 6.0 (5.5) as to “about”. Claims 3, 4, 35, 38, 45, 50, 51, 56, 57 and 65-67 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

12. Claims 23-25, for example, are indefinite because of the use of the term “less than about 5%”, “for up to at least 6 months” or “less than about 3 to about 4%”. The term “less than about 5%”, “for up to at least 6 months” or “less than about 3 to about 4%” renders the claim indefinite, it is unclear whether the water content in the lyophilized formulation is less than 5% as to “less than”, or is greater than 5% as to “about”, whether the GLP-2 formulation is stable less than 6 months as to “up to”, or, is greater than 6 months as to “about”, and the percentage of degradation of GLP-2 is in the range of 3 to 4% as to “about...to about”, or, is less than 3% as to “less than”. See also claims 26-30, 41, 42 and 47.

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13. Claim 42 is indefinite because of the use of the term “no more than about 2%”.

The term “no more than about 2%” renders the claim indefinite, it is unclear whether the water content is less than 2% as to “no more than”, or is greater than 2% as to “about”.

14. Claim 48 is indefinite because of the use of the term “up to about 24 hours”. The

term “up to about 24 hours” renders the claim indefinite, it is unclear the GLP-2

formulation is stable less than 24 hours as to “up to”, or, is more than 24 hours as to

“about”.

In response to the rejections in paragraphs 11-14, applicants indicate the same type of rejection has been withdrawn in the previous Office Action (Paper No. 10) in response to the argument presented in Paper No. 8 (page 14 of the response in the amendment March 16, 2004), which indicates a person of ordinary skill in the art would know the phrases refer to measurement variability (pages 3-4 of the response in Paper No. 8). The response has been considered, however, the argument is not found persuasive because the phrase, e.g., “the pH of the formulation is greater than about 6.0” indicates the pH can be less than, equal to, or greater than 6.0 as to the term “about”, however, the term “greater than” indicates the pH is higher than 6.0, thus it is not clear whether the pH is greater or less than 6.0 as to the term “greater than about”. Use of the term “the pH of the formulation is about 6.0 or greater” is suggested.

15. Claims 49-54, 57 and 63 are indefinite because the claims lack an essential step in

the method of treating a disease using the GLP-2 formulation. The omitted step is the

outcome for the treatment. Claims 49-54, 57 and 63 are also indefinite because of the use

of the term “a disorder, disease or condition for which treatment with GLP-2 is treated”.

The term “a disorder, disease or condition for which treatment with GLP-2 is treated”

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renders the claim indefinite, it is unclear what disease is treated. Claims 50-54, 57 and 63 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the same type of rejection has been withdrawn in the previous Office Action (Paper No. 10) in response to the argument presented in Paper No. 8 (page 14 of the response in the amendment March 16, 2004), which indicates claim 49 is a proper method claim, the “outcome of the treatment” is not a step, but is details about the method that is not necessary to make the claim a proper method claim, and the method of administration and the effective amount of formulation are factors that easily be determined by a person of ordinary skill in the art and are described in the specification (page 7, lines 27-33); and a person of ordinary skill in the art would also know the outcome of the treatment is to treat disorder, disease or condition for which treatment with GLP-2 is indicated (page 5 of the response in Paper No. 8). The response has been considered, however, the argument is not found persuasive because without citing the endpoint in a method claim, it is not clear whether the treatment is effective or not, and “to treat disorder” is not the endpoint of the treatment. Regarding the terms “a disorder, disease, or condition” and “gastrointestinal disease”, applicants indicate a person of ordinary skill in the art would know the disorders, diseases and conditions, including gastrointestinal diseases, for which treatment with GLP-2 is indicated because the specification indicates a therapeutically useful amount of GLP-2 is administered to treat a subject, which is described more fully in several cited patents and international documents, thus a person of ordinary skill in the art would refer to these documents to determine disorders, diseases, or conditions for which treatment with GLP-2 is indicated

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(pages 4-5 of the response in Paper No. 8). The response has been considered, however, the argument is not fully persuasive because these patents and international documents describe specific gastrointestinal diseases are treated with amounts of GLP-2 compounds, which are effective to reduce the pathology or symptom of these diseases, while the claims of the present invention do not identify the diseases being effectively treated, but cite the disorders, diseases, or conditions for which treatment with GLP-2 is indicated, thus it is not clear what disorders, diseases, or conditions are being treated in the claims.

17. Claim 59 is indefinite because of the use of the term “and/or”. The term “and/or” renders the claim indefinite, it is unclear whether the limitation after “and/or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”. Claim 59 is also indefinite as to the claim recites amino acid substitutions at various positions without indicating “SEQ ID NO:” of the reference sequence, it is not clear what amino acid sequence these positions are referring to.

### ***Conclusion***

18. Claims 2-4, 23-30, 34, 35, 37, 38, 41, 42, 44, 45, 47-54, 56, 57, 59, 63, 65-67 are rejected. It appears that claims 1, 5-22, 31-33, 36, 39, 40, 43, 46, 55, 58, 60-62, 64 and 68-76 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Chris Low*  
CHRISTOPHER S. F. LOW  
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June 4, 2004